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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,290

05/15/2006

Heinz Vollmers

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PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

EXAMINER

BRISTOL, LYNN ANNE

ART UNIT

PAPER NUMBER

1643

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,290	<b>Applicant(s)</b> VOLLMERS ET AL.	
	<b>Examiner</b> LYNN BRISTOL	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 72-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 72-97 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. Claims 72-97 are all the pending claims subject to analysis of unity of invention.
2. Claims 1-72 were canceled in the preliminary amendment of 5/15/06.

### ***Lack of Unity: Restriction***

3. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to the human SAM-6 monoclonal antibody that binds neoplastic cells and where the amino acid sequence of SEQ ID NOS: 1 and 3 correspond to the VL and VH domains of the human SAM-6 monoclonal antibody, respectively.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

The SAM-6 antibody was already known in the art prior to the international filing date (11/12/04) for this application. For example, Pohle et al. (Can. Res. 64: 3900-3906 (6/1/04); cited in the IDS of 3/15/07) describes the SAM-6 antibody produced from a trioma and which binds tumor tissues. Pohle does not explicitly teach the amino acid sequence for the VH and VL of the SAM-6 antibody, but absent a showing to the

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contrary, the sequences would be inherently identical to those of the instant claimed antibody.

Applicants have not provided a certified English language translation of the priority German language document for this application in order to claim benefit of the priority filing date of 11/14/03.

4. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 72-88, drawn to a polypeptide that binds neoplastic cells and is substantially identical in amino acid sequence to a sequence of SEQ ID NO: 1, 3 and/or a combination thereof, and where the polypeptide is an antibody.

Group II, claim(s) 89-91, drawn to a cell expressing a polypeptide comprising a sequence substantially identical in amino acid sequence to a sequence of SEQ ID NO: 1, 3 and/or a combination thereof.

Group III, claim(s) 92-94, drawn to a method for producing a hybridoma that expresses a polypeptide comprising a sequence substantially identical in amino acid sequence to a sequence of SEQ ID NO: 1, 3 and/or a combination thereof.

Group IV, claim(s) 95-97, drawn to a nucleic acid comprising the sequence of SEQ ID NO: 2 or 4 or further comprising a vector or further comprising a cell.

6. Three different products are presented in Groups I, II and IV. These 3 products do not share a common property or activity and do not share common core structures. The polypeptide is comprised of a linear strand of amino acid sequences, the cell expressing the polypeptide can be in a transgenic animal or transfected with a vector in vitro or a hybridoma, and the nucleic acid is a linear strand of nucleotide residues.

7. The method of Group III requires making a hybridoma expressing the polypeptide of SEQ ID NO: 1 and 3, which is not similar or necessarily overlapping with the products of Groups I, II and IV. The polypeptide is not the same as a hybridoma cell, the cell (Group II) may be a transgenic cell in a transgenic animal and not necessarily a hybridoma, and the nucleic acid is not the same as a hybridoma.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643